UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,914	03/16/2004	Nobuyoshi Karashima	ABE-022	9622

20374 7590 03/04/2009

KUBOVCIK & KUBOVCIK
SUITE 1105
1215 SOUTH CLARK STREET
ARLINGTON, VA 22202

EXAMINER	
VU, QUYNH-NHU HOANG	
ART UNIT	PAPER NUMBER
3763	
MAIL DATE	DELIVERY MODE
03/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,914	KARASHIMA, NOBUYOSHI	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/24/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Amendment filed on 11/24/08 has been entered.

Claims 9 and 12 are present for examination.

Claims 1-8, 10-11 and 13 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragarude (JP 2001-293016, cited from IDS and Applicant also admitted Prior Art, on pages 1-4 of Specification of current application) in view of Tapper (US 6,600,950), Goble et al. (US 5,944,715) or Fischer (US 7,040,893); Miyamoto et al. (US 2004/0062744); and Keusch (US 6,635,045).

Ragarude or AAPA discloses, (in Specification, on pages 1-4), a conventional iontophoresis-based metical device for sterilizing and treating a tooth infected with a pathogenic organism by iontophoresis is known. The conventional iontophoresis medical device was provided with an electric circuit having a voltage generator and a current supplied application apparatus (such as a hand piece), a positive electrode section and negative electrode section; wherein the positive electrode section was provided needle-shaped and deeply inserted into a tooth duct and the negative electrode section was directly attached to a part of a patient body (such as oral skin, wrist, or patient can grasp in a hand…). The negative electrode/terminal is formed by the metal probes with carried out the form of the needle (see para [0005 of Ragarude].

The method further comprising: contacting an oral lesion in the body tissue with a drug solution retained by a positive electrode section and it is necessary to discontinue treatment to apply the drug solution section several times (pg 3, lines 1-9 of the Spec); contacting a body tissue in the vicinity of the lesion with a second solution retained by a negative electrode section (pg 3, line 10+) to provide a closed electric circuit between these electrode section and the lesion (page 2, lines 7-16). Ragarude further discloses a treatment obtaining within as short a time as possible (see abstract of Ragarude); a current of 40 μA or lower (such as 5 μA is maximum, see para [0018 of Ragarude].

Ragarude or AAPA in the Specification does not disclose that:

a) the positive electrode in the form of a brush and the drug solution (in positive electrode) containing an amphoteric surface active agent having a sterilizing and disinfecting effect as a main ingredient;

b) the negative electrode in the form of a sponge; the second solution (in negative electrode) containing a sodium chloride solution having a concentration of 1 to 3%.

c) and the times of a conducting with current about 8 to 30 seconds.

For missing limitation a) above:

Goble discloses an electrically instrument for the treating tissue in cavities of the body. As noted that it can be used in side the mouth also. The device comprising a pair of electrodes (an active/positive electrode 14 and a return/negative electrode 18); wherein the active/positive electrode 14 in form of brush to contacts the tissue to be treated (col. 2, lines 57-65, col. 9, lines 55-63). Furthermore, it is well-known in the dental delivery tool to provide the brush for cleaning during a procedure.

Or Fischer suggests that a dental delivery tool with the step of brushing or cleaning with brush during a procedure (see abstract); brushing can occur by delivering a quantity of material to a surface (col. 27, lines 23-25).

Tapper discloses a method and apparatus for applying iontophoresis treatment to a biological subject wherein electrical treatment current between a pair of electrodes. Tapper further discloses that the drug solution (in positive or active electrode) containing amphoteric surface active agent to enhance

the electrical conductivity, permeability and penetration at the site (col. 6, lines 42-51, col. 13, lines 59-63). Tapper further discloses that the positive/active electrode is a "carrier drug" (reservoir), (col. 11, lines 23-41, col. 14, lines 48-52). Tapper does not including a sterilizing and disinfecting effect in the amphoteric surface agent.

Meanwhile, Miyamoto suggests that the sterilizing disinfectants based on amphoteric surfactants such as alkylpolyaminoethylglycine hydrocholorides (similar to drugs that Applicant discussed on page 11, lines 16-18 of Specification).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of AAPA with a positive electrode in form of brush, as taught by Goble or Fischer, in order to clean and delivery a quantity of material to a treatment sites. It would have been obvious at the time the invention was made to a person having ordinary skill in the art to obtain the amphoteric surface agent having a sterilizing and disinfecting effect, as taught by Tapper and Miyamoto, for the benefits of enhancing the electrical conductivity, permeability and penetration at the site and the solution alkylpolyaminoethylglycine hydrocholorides as sterilizing and disinfecting effect.

For missing limitation b) above: the negative electrode in the form of a sponge; the second solution (in negative electrode) containing a sodium chloride solution having a concentration of 1 to 3%.

Keusch discloses a device and method for iontophoresis of electrically drug delivery comprising: an anode/positive electrode; a return/negative electrode maybe a hydrogel and contains a salt such as NaCl with a concentrate about 0.9% (almost 1%); wherein the hydogel reservoir include a layer of scrim (fabric or nonwoven polymer or equivalent to sponge for absorb the drugs) (col. 7, lines 5-17, lines 38-60).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of AAPA with a negative electrode in form of sponge/nonwoven polymer/fabric) with the concentrate about 0.9%, as taught by Keusch, for enhancing the electrical conductivity and preventing corrosion. As noted that, the concentration of Keusch is almost close to the amount of claimed invention requires, therefore, it does not much different change. Beside that,

it would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the amount 1-3% concentration, since it has been held that where in the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

For missing limitation c) above: the times of a conducting with current about 8 to 30 seconds.

Regarding about the value of conducting current of 8 to 30 seconds, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the conducting time between 8-30 seconds, since it has been held that where in the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

It has been that a recitation "for 8 to 30 seconds" with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed from a prior art satisfying the claimed method or structural limitations. Ex Pane Masham, 2 USPQ F. 2d 1647 (1987).

Conclusion, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Ragarude/AAPA with an amphoteric having a sterilizing and disinfecting effect, as taught by Tapper and Miyamoto, to enhance the electrical conductivity permeability and penetration at the treatment site and sterilizing disinfectant purpose. One skill in the art would recognize that providing a brush in the device, as taught by Goble or Fischer, for cleaning and delivery the drugs during a procedure. With the second solution contained sodium chloride retained in formed of sponge, as taught by Keusch, in order to enhance the electrical conductivity and able to retain the solution.

Response to Arguments

Applicant's arguments with respect to claims 9 and 12 have been considered but are moot in view of the new ground(s) of rejection.

1. Applicant argues that the amphoteric surface active agent in Tapper is provided so as to improve the permeability and penetrability of another drug-not to provide a sterilizing and disinfecting action.

Tapper does not provide a sterilizing and disinfecting action. However, Miyamoto suggests amphoteric surface active agent having a sterilizing and disinfecting action (see rejection above).

2. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763